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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,176	01/20/2004	Robert H. Frater	4398-323	6667
23117	7590	07/14/2005	EXAMINER	
NIXON & VANDERHYE, PC			LEWIS, AARON J	
901 NORTH GLEBE ROAD, 11TH FLOOR			ART UNIT	
ARLINGTON, VA 22203			PAPER NUMBER	

3743

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/759,176	Applicant(s) FRATER ET AL.	
	Examiner AARON J. LEWIS	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-50,75-80 and 125-146 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-50,75-80,125-130,137-139 and 143-146 is/are rejected.
- 7) ☒ Claim(s) 131-136 and 140-142 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "variable projected area of the gusset" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 47,78,137 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The projected area of the gusset being variable in dependence upon the distance between the mask shell and the cushion is not described in the specification in any manner that makes clear that there exists a plurality of projected areas of the gusset.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 47-50,75-80,125-130,137-139,143-146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venegas ('297).

As to claim 47, Venegas discloses a breathable gas mask arrangement, comprising: a mask shell having a portion (18) adapted to receive a supply of pressurized breathable gas (20) and a user side (12); a gusset portion (14) having a first side (32) attached to the user side of the shell and having a second side (18); a cushion (12) having a first portion constructed and arranged to attach to the second side of the

gusset portion and a second portion (26) constructed and arranged to contact a user's face in use and provide a seal between the mask arrangement and the user's face; and a headgear (22) constructed and arranged to attach the mask shell to the user; wherein the gusset portion is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion (col.4, lines 42-51), an interior of the gusset portion being exposed to the supply of pressurized breathable gas and having a projected area on the user's face A_g which is greater (col.4, lines 28-31) than an area A_c of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the cushion on the user's face, and a ratio of A_g/A_c is greater than 1.00 (col.4, lines 28-31), a change in total force of the mask on the face F_m being generally directly proportional at a given operating pressure to a displacement of the mask shell toward the user's face (col.4, lines 47-51) from an initial seal position within a range of such mask shell displacement. As to the projected area of the gusset being variable in accordance with alterations of the distance between the mask shell and the cushion, Venegas (fig.4) illustrates gusset (14) to have pleats some of which extend inwardly when not exposed to pressurized gas and the relative position of the crests of the inwardly extending pleats relative to the crests of the outwardly extending pleats projects a smaller area onto a wearers face. The inward extension of the pleats reduces the projected area of the gusset because inwardly extended pleats have not ballooned outwardly under pressure of breathable gas. As pressurized gas is applied to the mask

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of Venegas, the inwardly directed pleats of the gusset (14) expand outwardly to the edge of the first side (32) thereby increasing the projected area.

The difference between Venegas and claim 47 is a range of mask shell displacement of about 6-25 mm.

Venegas (col.4, lines 47-51) discloses expansion of the mask shell causing it to be pressed against a user's face with sufficient force to form an airtight seal; accordingly, it stands to reason that the abovementioned expansion of the mask shell includes movement towards a user's face in order to achieve the airtight seal. The amount of movement of the shell towards a user's face including a distance within a range of 6-25mm can be arrived at (i.e. adjusted using headgear 22 as disclosed at col.3, lines 57-59) through mere routine obvious experimentation and observation in dependence upon the patient's size, shape and age and comfort level with a given degree of tightness.

As to claim 48, Venegas (col.4, lines 47-51) as discussed above with respect to claim 47, discloses expansion of the mask shell causing it to be pressed against a user's face with sufficient force to form an airtight seal; accordingly, it stands to reason that the abovementioned expansion of the mask shell includes movement towards a user's face in order to achieve the airtight seal. The amount of movement of the shell towards a user's face including a distance within a range of 10-20mm can be arrived at (i.e. adjusted using headgear 22 as disclosed at col.3, lines 57-59) through mere routine obvious experimentation and observation in dependence upon the patient's size, shape and age and comfort level with a given degree of tightness.

As to claim 49, Venegas (col.4, lines 28-31) discloses the ratio of A_g/A_c to be 1.2-1.6 which includes the portion of the claimed range of 1.5-4.0.

As to claim 50, Venegas discloses the gusset portion (14) to include a single gusset having a flexible sidewall (figs.1-3) with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section (fig.2) when exposed to the supply of pressurized breathable gas. That is, the gusset portion being an expansible member (co.3, line 2) is fully capable of expanding outwardly in a manner which resembles a "generally rounded" cross section when inflated with pressurized breathable gas.

As to claim 75, Venegas (figs.1-3) discloses a mask assembly attachable to a user for receiving and supplying pressurized air to the user, comprising: a cushion (26) for contacting a user's face; and a suspension mechanism (14) axially movably supporting the cushion and exposed to the pressurized air to provide a first axial spring force to the cushion proportional to a pressure of the air.

Venegas lacks express disclosure of a second axial force on the cushion due to the pressurized air acting directly on the cushion which is at least 30% less than the first axial spring force; however, fig.4 of Venegas illustrates that the pressurized air acts through the suspension mechanism to provide a sealing force on the mask rather than acting directly on the cushion (26) to provide a sealing force. It stands to reason that any force on the cushion from the pressurized gas is negligible compared to the force on the cushion from through the suspension mechanism (14); consequently, any force from the pressurized gas that is acting directly on the cushion from the pressurized gas

is at least 30% less than the force of the pressurized gas acting through the suspension mechanism (14).

Claim 76 is included in Venegas for the reasons set forth above with respect to claim 75.

As to claim 77, Venegas discloses the gusset portion (14) to include a single gusset having a flexible sidewall (figs.1-3) with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section (fig.2) when exposed to the supply of pressurized breathable gas. That is, the gusset portion being an expansible member (co.3, line 2) is fully capable of expanding outwardly in a manner which resembles a "generally rounded" cross section when inflated with pressurized breathable gas.

Claims 78-80 are substantially equivalent in scope to claims 75-77 and are included in Venegas for the reasons set forth above with respect to claims 75-77. As to the claimed "second variable projected area" recited in claim 78, Venegas (fig.4) illustrates a suspension mechanism (14) having a variable projected area (i.e. Venegas (fig.4) illustrates gusset (14) to have pleats some of which extend inwardly when not exposed to pressurized gas and the relative position of the crests of the inwardly extending pleats relative to the crests of the outwardly extending pleats projects a smaller area onto a wearers face. The inward extension of the pleats reduces the projected area of the gusset because inwardly extended pleats have not ballooned outwardly under pressure of breathable gas. As pressurized gas is applied to the mask of Venegas, the inwardly directed pleats of the gusset (14) expand outwardly to the edge of the first side

(32) thereby increasing the projected area.). As to the first projected area being at least 30% greater than the second projected area, Venegas (col.4, lines 29-30) discloses at least a 30% greater first projected area.

As to claims 125 and 126, Venegas discloses the ration of A_g/A_c to be 1.2-1.6; however, inasmuch as Venegas (col.3, line 60-col.4, line 34) discloses varying the cross sectional area of the piston relative to the cross sectional area of the facial unit in order to generate sufficient sealing force, it would have been obvious to modify the cross sectional areas of the piston and facial unit to any desired ration including greater than 1.6 as an obvious matter of design choice with no criticality seen in any particular ratio. One of ordinary skill would have recognized the need to tailor the mask of Venegas to provide sufficient sealing forces to accommodate faces of varying sizes and shapes from children to adults. In order to achieve a mask having sufficient sealing forces, it would have been necessary to vary the A_g/A_c ratio in Venegas in order to provide a mask capable of providing a plurality of sealing forces.

As to claim 127, Venegas discloses a single gusset (14).

As to claim 128, Venegas as discussed above with respect to claim 47 also discloses a flexible sidewall (figs.1-3) with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section (fig.2) when exposed to the supply of pressurized breathable gas. That is, the gusset portion being an expansible member (co.3, line 2) is fully capable of expanding outwardly in a manner that resembles a "generally rounded" cross section when inflated with pressurized breathable gas.

As to claim 129, Venegas (fig.4) illustrates gusset (14) to have pleats some of which extend inwardly when not exposed to pressurized gas and the relative position of the crests of the inwardly extending pleats relative to the crests of the outwardly extending pleats projects a smaller area onto a wearers face. The inward extension of the pleats reduces the projected area of the gusset because inwardly extended pleats have not ballooned outwardly under pressure of breathable gas. As pressurized gas is applied to the mask of Venegas, the inwardly directed pleats of the gusset (14) expand radially outwardly to the edge of the first side (32) thereby increasing the projected area.

As to claim 130, the piston assembly (14) of Venegas is expressly disclosed as comprising virtually any apparatus or structure, the volume of which is able to expand in response to increased pressure. While the piston assembly of Venegas is illustrated as being a bellows, it would have been obvious to modify the piston assembly of Venegas to be any functionally equivalent structure including a spring as an obvious matter of design choice and because Venegas expressly discloses that it may comprise virtually any apparatus or structure.

As to claim 137, Venegas as discussed above with respect to claim 47, also teaches the projected area of the gusset being variable in accordance with alterations of the distance between the mask shell and the cushion. Venegas (fig.4) illustrates gusset (14) to have pleats some of which extend inwardly when not exposed to pressurized gas and the relative position of the crests of the inwardly extending pleats relative to the crests of the outwardly extending pleats projects a smaller area onto a wearers face. The inward extension of the pleats reduces the projected area of the gusset because inwardly

extended pleats have not ballooned outwardly under pressure of breathable gas. As pressurized gas is applied to the mask of Venegas, the inwardly directed pleats of the gusset (14) expand outwardly to the edge of the first side (32) thereby increasing (i.e. varying) the projected area.

As to claim 138, Venegas (fig.4) illustrates gusset (14) to have pleats some of which extend inwardly when not exposed to pressurized gas and the relative position of the crests of the inwardly extending pleats relative to the crests of the outwardly extending pleats projects a smaller area onto a wearers face. The inward extension of the pleats reduces the projected area of the gusset because inwardly extended pleats have not ballooned outwardly under pressure of breathable gas. As pressurized gas is applied to the mask of Venegas, the inwardly directed pleats of the gusset (14) expand radially outwardly to the edge of the first side (32) thereby increasing the projected area.

As to claim 139, the piston assembly (14) of Venegas is expressly disclosed as comprising virtually any apparatus or structure, the volume of which is able to expand in response to increased pressure. While the piston assembly of Venegas is illustrated as being a bellows, it would have been obvious to modify the piston assembly of Venegas to be any functionally equivalent structure including a spring as an obvious matter of design choice and because Venegas expressly discloses that it may comprise virtually any apparatus or structure.

As to claim 143, Venegas discloses headgear comprising at least one strap (22).

As to claims 144 and 145, once the headgear of Venegas (col.4, lines 35-56) is adjusted to accommodate a given wearer, there is no disclosure of having to readjust

the headgear to maintain the seal between the mask arrangement and a wearer's face; rather, it is the application of pressurized breathable gas through the mask that causes the maintenance of the seal. Further, the headgear of Venegas is adjusted to bring the mask into contact with a wearer's face (col.4, lines 53-56) and it stands to reason that the headgear is not adjusted in a manner that would cause the mask to exert a contact pressure (i.e. due to headgear adjustment alone) against a wearer's face that exceeds contact pressure such that it would have caused a wearer to be uncomfortable.

As to claim 146, Venegas discloses a single gusset (14).

Allowable Subject Matter

6. Claims 131-136,140-142 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicant's arguments with respect to claims 47-50,75-80,125-146 have been considered but are moot in view of the new ground(s) of rejection.

The variability of the projected area of the gusset of Venegas is the subject of a new position in the body of the rejection as set forth above.

Applicant's arguments regarding a triangular cross section to a rounded cross section are not persuasive because fig. 4 of Venegas illustrates gusset (14) being in triangular cross section due to the pleating arrangement of the bellows and due to the overall triangular shape of the sidewalls (16). The gusset is disclosed as being an expandable bellows (col.3, line 25); accordingly, it stands to reason that upon being

pressurized by breathable gas, the bellows expands outwardly and presents a shape consistent with that of a "generally rounded cross section" due to its expansion.

Applicant's arguments regarding claim 75 are not persuasive because the primary force acting on cushion (12) is from piston assembly (14) as discussed at col.3, line 60-col.4, line 35 with particular respect to the relative sizing of the piston arrangement relative to the cushion being critical to the quality of the mask/face seal.

Conclusion

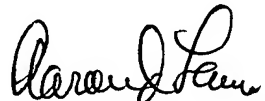
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
July 09, 2005